



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA-2011-F-0172]

A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods--Part II (Menu Labeling Requirements in Accordance with the Patient Protection Affordable Care Act of 2010); Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods--Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11); Draft Guidance for Industry.” The draft guidance, when finalized, will help certain restaurants and similar retail food establishments comply with the menu labeling requirements, including the requirements to provide calorie and other nutrition information for standard menu items, including food on display and self-service food.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by

[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lynn Szybist, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods--Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11); Draft Guidance for Industry.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

In the Federal Register of December 1, 2014 (79 FR 71156), we published a final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments; the rule is codified at Title 21 of the Code of Federal Regulations at § 101.11 (21 CFR 101.11). The final rule implements requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)(5)(H)), which in general, requires that restaurants and similar retail food establishments that are part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items, provide calorie information for standard menu items (including food on display and self-service food), provide, upon request, additional written nutrition information for standard menu items, and comply with other requirements described in section 403(q)(5)(H) of the FD&C Act. The draft guidance uses a question and answer format and is intended to help restaurants and similar retail food establishments covered by the final rule comply with the nutrition labeling requirements of the final rule.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 101.11(d), (c)(3), and (b)(2) have been approved under OMB Control No. 0910-0783.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: September 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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